USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 2/14/2017
GAIN Report Number: IN7026

India

Post: New Delhi

Draft Regulation on Product Approval Published in Indian Gazette

Report Categories:
Sanitary/Phytosanitary/Food Safety
Exporter Guide
Food and Agricultural Import Regulations and Standards - Narrative

Approved By:
Jonn Slette

Prepared By:
Radha Mani

Report Highlights:

The Food Safety and Standards Authority of India (FSSAI) published in India's official gazette a draft regulation on new product approval procedures.

General Information:

DISCLAIMER: The information contained in this report was retrieved from Government of India and World Trade Organization (WTO) websites: http://www.fssai.gov.in/ and www.wto.org. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

On January 31, 2017, FSSAI published a draft regulation on new product approval procedures in the Official Gazette of India and invited a 30-day comment period only from the domestic stakeholders. The comment period expires on March 11, 2017. FSSAI has termed these categories of food or food ingredients as "non-specified food and food ingredients."

The draft regulation outlines new product approval procedures for the following food and/or food ingredients:

a. Novel foods or food containing novel ingredients with no history of human consumption in India;
b. Food ingredients with a history of human consumption in India, but are not specified under any other regulations made under the Food Safety and Standards Act, 2006;
c. New additives and processing aids; and
d. Foods manufactured or processed through novel technologies.

For readers' convenience, the definition of novel foods as defined by FSSAI is pasted below.

13. Novel food.– (1)(i) For the purposes of these regulations novel food is a food that-

(a) may not have a history of human consumption; or

(b) may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption; or

(c) a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.

(ii) No novel food shall be manufactured or imported for commercial purpose without the prior approval of the Food Authority by filing an application along with all relevant documents and details as specified by the Food Authority from time to time.

(2) The labelling of novel food shall be-

(i) in accordance with the specific labelling requirements, if any; or

(ii) specific to claims relating to the novel product; or

(iii) as per the category notified by the Food Authority in the specific regulations.

Background:

A similar draft notice was published by FSSAI on October 4, 2016, soliciting comments from WTO member countries for 60-days period after the WTO published the notice on its website, which occurred on October 17, 2016 (G/SPS/N/IND/163). Subsequently, the comment period for WTO members expired on December 16, 2016. For additional details on the draft notice, please refer to GAIN IN6132.

The full text of the notification as well as the press note is pasted at the end of this report and is also available on the FSSAI's website www.fssai.gov.in/

Press note

Food Safety and Standards (Approval for non-Specified Food and Food Ingredients) Regulations, 2017

FSSAI has notified draft regulations on Food Safety and Standards (Approval for non-Specified Food and Food Ingredients) Regulations, 2017 inviting comments and suggestions within a period of 30 days from the date of publication of the notice.

2. After implementation of the Act and the Regulations framed thereunder with effect from 5th August 2011, and the fact that the safety assessment and approval for the non-standardized food was a new concept, the FSSAI introduced a Product Approval system through advisories as a means to undertake safety assessment of the food products and products containing ingredients which do not have standards.

3. However, in view of the Hon'ble Supreme Court order vide dated 19.08.2015, it was no longer possible to continue the process of product approvals for non-standardized food products/ ingredients in the absence of legitimate regulations.

4. In order to address the situation arising after discontinuation of the product approval system, FSSAI has amended the provision pertaining to proprietary foods in relevant regulation and also notified the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. With these developments, a larger number of products, that would have otherwise required specific approvals from Food Authority, got covered. However, there are several food products/ ingredients which are still not covered in the any of the regulations made under FSS Act, 2006.

5. Consequently, to provide the opportunity to Food Business Operators to innovate the new food products, FSSAI came up with this draft regulation on Food Safety and Standards (Pre-Market Approval for Non-standardised Food) Regulations, 2017.

7. This regulation covers the following articles of food or food ingredients:

(a) novel food or food containing novel ingredients not having a history of human consumption in the country;

(b) food ingredients with a history of human consumption in the country but not specified in any other regulations made under the Act;

(c) new additives and processing aids;

(d) food manufactured or processed with the use of novel technology.

The above regulation will be finalised after considering the comments/ suggestions from the stakeholders.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 31st January, 2017

F. No. 12/PA Regulation/Dir (PA)/FSSAI-2016.—The following draft of the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2016, which the Food Safety and Standards Authority of India proposes to make with the previous approval of the Central Government, in exercise of the powers conferred by clause (v) of sub-section (2) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby published as required by sub-section (1) of section 92 of the said Act, for the information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of a period of thirty days from the date on which the copies of the Gazette containing this notification is published are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi – 110 002 or send to the email address of Authority at regulation@fssai.gov.in

The objections or suggestions, which may be received from any person with respect to the said draft regulations before the expiry of the period specified above, shall be considered by the Food Safety and Standards Authority of India.

Draft regulations

1 **Short title and commencement.**—These regulations may be called the 'Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.'

2. **Definitions.**—(1) In these regulations, unless the context otherwise requires:-

(a) "Act" means the Food Safety and Standards Act, 2006 (34 of 2006);

(b) "Approval" means a permission to manufacture, distribute, sell or import any article of food or food ingredients, intended directly or indirectly for human consumption, that has not been permitted under any other regulation made under the Act;

(c) "Food Authority" means the Food Safety and Standards Authority of India established under section 4 of the Act.

(2) The words and expressions used herein and not defined, but defined in the Act or rules or regulations made thereunder, shall have the meaning as assigned to them in the Act, rules or regulations.

3. **Procedure for grant of prior approval.**—(1) The manufacturer or importer of articles of food shall submit an application in **FORM I, or FORM II, or FORM III, or FORM IV, or FORM V, or FORM VI,** as the case may be, along with requisite documents and fee to the Food Authority.

(2) The Food Authority shall scrutinize the application and other information stated in FORM I, or FORM II, or FORM III, or FORM IV, or FORM V, or FORM VI.

(3) The Food Authority may direct the applicant to submit additional supporting documents, data or clarifications, if required.

(4) The Food Authority may either grant approval or reject the application, as per FORM VII, on the basis of the safety assessment of the articles of food.

(5) Where the approval is granted, the food business operator shall submit certificate of analysis of the production parameters relating to chemical, nutritional, microbiological, heavy metals, pesticide residues and naturally occurring toxicants to the Food Authority.

(6) The food business operator may file an appeal before the Chairperson, Food Authority, against any decision of rejection of his application.

(7) A food business operator, who is aggrieved by the decision of the Chairperson, Food Authority, may file review petition to be placed for consideration in the meeting of the Food Authority.

(8) The Food Authority may, for reasons to be recorded in writing, revoke or suspend any approval granted to any food business operator.

(9) The Food Authority may review from time to time, the amount of fee for filing an application.

(10) If the food business operator has reason to believe that the food for which the approval has been granted involves any risk for health, he shall immediately suspend the import, manufacture, sale, or

distribution of such articles of food and take steps to recall the same under intimation to Food Authority in accordance with the provisions of the Food Safety and Standards (Food Recall) Regulation, 2016.

(11) The Food Safety Officers and Designated Officers shall immediately inform the Food Authority of any complaint received regarding safety of food approved by the Food Authority under these regulations.

4. Prior approval for manufacture, storage, sale, distribution, import, etc.—(1) No person shall manufacture, store, sell, distribute or import the following articles of food or food ingredients except with the prior approval of the Food Authority, namely:—

(a) novel food or food containing novel ingredients not having a history of human consumption in the country;

(b) food ingredients with a history of human consumption in the country but not specified in any other regulations made under the Act;

(c) new additives and processing aids;

(d) food manufactured or processed with the use of novel technology.

(2) The provisions of these regulations are in addition to and not in derogation of any rules or regulations made under the Act.

5. The food business operator shall apply for the license as per the procedure specified in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, after grant of approval as per **FORM VII.**

FORM I

[See regulation 3 (1) and 3 (2)]

Application format for approval of non-specified food and food ingredient

Name of the applicant:

Mobile No. / Phone No. :

E-mail:

Name of the organisation:

Licence number if any:

Nature of Business:

Organisational Background:

Address of the organisation:

City:

State/UT:

Note: All communications will only be made through the above email and phone number.

FORM II

[See regulation 3 (1) and 3 (2)]

Persons applying for novel food or food containing novel Ingredients or processed with the use of novel technology shall furnish the following information, namely:—

I. The target group for the said proposed food, if any:

1. Name of the proposed product/Ingredient:
2. Justification of the name of the proposed product:
3. Provide the detailed composition of the product (with quantity of the ingredients and additives added in the product)
4. Source of ingredient (animal, chemical, botanical or micro-biological)

In case of animal, botanical or micro-biological source genus and species may be mentioned

(a) Any New Ingredient(s) [Please specify if the products had one or more new ingredients] meaning any ingredients which as on date is not listed in Food Safety and Standards Regulation, or an ingredient which has been introduced for the first time in India;

(b) Evidence proving that the product / ingredient is safe

5. Please provide the documentary evidence regarding regulatory status of the ingredients.

6. Indicate the recommended daily allowance levels (as specified by Indian Council of Medical Research) for vitamins, minerals and such other nutrients where recommended daily allowances are specified.

7. Functional use of ingredient or product:

(a) Specify the functional use of the proposed product in the target group for human consumption;

(b) A brief description with documentary evidence of the same may be provided along with justification of data etc. for the quantity used.

8. Provide intended use of the new product:

(a) Specific benefit to the consumers or food manufacturers, if the proposed food product/ingredient is allowed;

(b) Specific advantages/disadvantages of the proposed food product to consumers and manufacturers along with justification, supported with documentary evidence;

(c) Any other perceived use of the manufacture and resultant advantages or disadvantages may also be provided.

9. Certificate of analysis from third party National Accredited Board of Laboratories or International Laboratories Accreditation Cooperation recognised laboratories shall be provided which demonstrates the compliance of the ingredients or products to the specifications as claimed by the applicant. The certificate of analysis shall include chemical parameters, nutrient levels, calorific value, metals contaminants (Pb, Cd, As, Cr, Cu, Sn, Hg, Ni), naturally occurring toxic substances, aflatoxins, pesticide residues, TPC, Y&M, E-Coli, Coli Form and freedom from Pathogenic organisms, and other chemical parameters. The validated test method as needed for the analysis (with information on Limit of Detection, Limit of Quantification, sensitivity, repeatability, specificity and other test methods) shall be provided with references.

10. Proposed label in compliance with section 23 of the Act and Food Safety and Standards (Packaging and Labeling) Regulations, 2011 to be attached with the following heading :—

'PROPOSED LABEL FOR APPROVAL'

11. Method of manufacture: Please provide the process used for manufacture of the product in detail.

12. Real time or accelerated Shelf Life or Stability of product (shelf life studies) shall be provided.

13. Specific conditions of storage must be provided along with detailed directions for use and expected ill effect due to failure to store the product under optimal conditions.

14. History of consumption of product (attach supporting documents)

(a) Geographical area of use (with established history of safe use in at least two countries, regulated by the Food regimes prevalent in EU, USA, Canada, Australia, Japan and China;

(b) Average quantity of consumption;

(c) Positive effects;

(d) Negative or adverse effects.

15. Safety Information: (Documents on risk assessment or toxicity studies to be attached)

(a) The information shall be based on safety or risk assessment review from published studies and safety studies conducted on the ingredient and food product by the applicant:

(b) Safety information (literature based and if any additional study conducted):

(c) Information on human studies, if any;

(d) Toxicological studies;

(e) Results of Ame's tests to test mutagenecity, chromosomal aberration tests, studies for reproductive toxicity, prenatal developmental toxicity studies;

(f) Provide evidence to demonstrate that the proposed product or the ingredient will not adversely affect any specific population groups that is pregnant women, lactating mothers, children, elderly or any other vulnerable group;

(g) History of new ingredient/product in other countries (Documents to be attached);

(h) Allergenicity: Attach published or unpublished reports of allergenicity or other adverse effects in humans associated with the food consumption, Attach reports prepared by World Health Organisation or by other national or international agencies responsible for food safety or public health like Codex, United States Food and Drug Administration, European Union, Food Standards Australia New Zealand and other agencies;

(i) Information on dietary exposure, nutritional impact and potential impact on the consumer.

16. Regulatory Status: Mention the countries where the product or ingredient is permitted for direct or indirect human consumption as food. If so, provide the level and purpose of consumption by the consumers with the relevant regulations.

17. Copy of agreement of relationship of applicant and manufacturer and other entities involved in the food business of the proposed product, namely, marketer, importer, re-packer.

18. List of documents attached: The applicant shall attach an indexed list of documents in support of the application and identify these in relation to the information code herein.

21. All data documentary evidence provided by the applicant shall be from international peer reviewed journals, international bodies including World Health Organisation and Food and Agriculture Organisation. Only complete records or studies shall be provided.

Name and signature of the Applicant.

FORM III

[See regulation 3 (1) and 3 (2)]

Application for food ingredients with a history of human consumption in the country but not specified in any regulation under the Act:—

(a) Product name;

(b) Proprietary name;

(c) Food Category System code;

(d) Manufacture or Intend to manufacture or importer or wish to Import or market or wish to market;

(e) Copy of license (if any);

(f) Detail Composition with quantity of ingredients and additives;

(g) Regulatory status of the additives;

(h) Source of the ingredients and additives (animal, chemical, botanical or micro-biological) In case of animal, botanical or micro-biological source genus and species may be mentioned;

(i) End use declaration;

(j) Complete Certificate of analysis;

(k) Shelf life stability datasheet;

(l) Label and Claims if any;

(m) Copy of agreement;

(n) Manufacturing process in brief;

(o) Declaration whether Recommended Daily Allowance values of ingredients (like mineral/ vitamins/amino acids/protein/metal etc.) are as per Indian Council of Medical Research guidelines along with the age group.

FORM IV

[See regulation 3 (1) and 3 (2)]

Application format for new additives.

(1) Common name and Chemical name

(2) Category or Class name of the additive (Please give the functional name of the additive, namely, Emulsifier/Preservatives/permitted sweeteners/anti-oxidants and other additives)

(3) Name, INS number and quantities of the food additives.

(4) Purity (Food grade)

(5) Acceptable Daily Intake or status as per Codex

(6) Level of use applied for

(7) Source of the ingredient(animal, chemical, botanical or micro-biological)

(8) Risk Assessment by appropriate agency.

(9) Brief description of the functional role of the additive in the food (S) for which approval is required,

(10) Regulatory status in Food Safety and Standards (Food Product Standards and Food Additives) Regulation 2011

(11) If response to the above is negative, Please give International approval status like CODEX, Code of Federal Regulations (United States), European Food Safety Authority, Food Standards Australia New Zealand, and other agencies.

(12) Certificate of analysis as in Form II

(13) Shelf life stability data sheet

(14) Label as per Food Safety and Standards (Packaging and Labelling) Regulations, 2011

(15) Safety information

(16) Method of manufacture

(17) Method of analysis

(18) Copy of agreement

(19) In case of flavouring agent specify whether it is natural or nature identical or artificial or synthetic and in case of colouring agent provide (Colour Index) colour number where applicable.

(20) If the additive is used as a processing aid in the product, specify any residual levels that may be present in the final product.

FORM V

[See regulation 3 (1) and 3 (2)]

Application format for processing aids and enzymes.

(1) Name

(2) Synonym

(3) Molecular weight, enzyme activity, purity, water content, ash content, microbial limit, storage standards may be specifically provided.

(4) Specification

(5) Source

(6) Certificate of analysis as specified in Form II

(7) Shelf life stability data sheet

(8) Label as per Food Safety and Standards (Packaging and Labelling) Regulations, 2011

(9) Safety information

(10) Manufacturing process

(11) Method of analysis

(12) Copy of agreement

(13) Risk assessment

(14) International practices

(15) Effect of food enzyme or processing aids in the final food.

(16) End use (specify food in which it is to be used)

(17) Residual limit in the final product.

(18) Acceptable Daily Intake

(19) Toxicity level

(20) Adverse effect (If any)

FORM VI

[See regulation 3 (1) and 3 (2)]

Application format for articles of food and food ingredients consisting of or isolated from microorganisms, fungi or algae:—

Data required for microorganisms used as Food (Directly Fed) or Used as a Source of Food Ingredients				
S. No.				
1.	Nature of microbe	Bacterium	Yeast	Fungus
2	Name of the microbe	Genus	Species	Strain
3	Source	Indigenous	Imported	
		Isolated	Culture Collection	
4	If locally isolated	Deposited in the National Culture Collection (e.g. Microbial Type Culture Collection, National Centre for Disease Control)	Yes	No
5	If deposited in Culture Collection	Name and Address of Culture Collection	Reference No.	Receipt (Copy)
6	If bought from National Culture Collection	Name and Address of Culture Collection	Reference No.	Receipt (Copy)
7	If imported and privately Isolated	Country of origin		
		Name and Address of the Foreign Organization/Industry	Reference No.	Receipt (Copy)

8	If bought from International Culture Collection (e.g. American Type Culture Collection, Journal of Clinical Microbiology)	Name and Address of International Culture Collection	Reference No.	Receipt (Copy)
9	Material Transfer Agreement between exporter/foreign entity and importer/manufacturer in India	Yes (Copy)	No	
10	If the organism has been genetically manipulated.	Yes	No	
11	Type of genetic manipulation	Induced mutation	Recombinant DNA Technology	
12	If induced mutation	The nature of mutation	The name of the genealtered	
13	If Recombinant DNA Technology	The nature and Sourceof plasmid Vector		
		Foreign gene insert	Nature	Source
		Whether vector contains antibiotic resistance gene?	Yes/No	The name of antibiotic and concentration
14		Any other markers on vector	Yes/No	Type
15	Any precautions/safety Issues specified with the vector/ foreign gene			
16	Any Institutional Bio Safety mechanism in place			
17	Safety/Generally Recognised as Safe Status of the microbe	Copy		
18	Declaration by the Manufacturer or importer regarding safety and end use	The undersigned verifies that all ingredients are approved for use by the Export Country National Regulator or appear on their Generally Recognised as Safe list (Name of the Regulatory Agency), and each product is intended for human consumption and is available for sale in the country of origin without restriction.		

(1) Composition of the product

(2) Certificate of analysis as specified in Form II

(3) Shelf life stability data sheet

(4) Label as per Food Safety and Standards (Packaging and Labelling) Regulations, 2011

(5) Manufacturing process

(6) Method of analysis

(7) Safety information

(8) Copy of agreement

FORM VII

Approval

[See regulation 3(4) and regulation 5]

1. Application details:

Subject:	Application for Approval – reg.
Application No:	
Date of application:	
Name of the FBO/ applicant:	
Registered office address:	
Authorised person:	
Name of the proposed food product:	

2. Application status:

Approval status:	Approved/Rejected
Product category:	
Product name:	

3. Composition:

Ingredients		**Food Additives**		
		Name	INS No.	Limits (GMP or mg/Kg)

4. Conditions for approval:

(Authorised Signatory)

5. Reasons for rejection, if any:

PAWAN AGARWAL, Chief Executive Officer

[ADVT. III/4/Exty./407/16(187)]

Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.